MEDI-CAL
MEDICAL SUPPLIES
AND
ENTERAL FORMULAS
REVIEW PROCEDURES

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REVIEW PROCEDURES

GENERAL INFORMATION

This document represents the standard medical supplies/enteral formulas review procedures used by the Department of Health Services (Department) that incorporate specific criteria (safety, efficacy, misuse potential, essential need, and cost) to be used by Department staff in the Medi-Cal Contracting Section for making recommendations and decisions regarding addition, deletion, or retention of medical supplies/enteral formulas on the Medi-Cal List of Contract Medical Supplies/Enteral Formulas (List).

The medical supplies/enteral formulas subject to review are those that would be dispensed to fee-for-service Medi-Cal beneficiaries and billed by pharmacy providers.

The Medi-Cal Contracting Section will retain all records associated with recommendations and decisions regarding addition, deletion, or retention of medical supplies/enteral formulas on the List for a period of two years.

Confidentiality requirements are applicable to the *Product Category Review* AND the *Petition* processes described in this document. Confidentiality is required of all participants engaged in the contracting process. All anti-trust and collusion laws must be strictly adhered to by all. This includes, but is not limited to:

- **active promotion** of products proposed for addition to the List shall not occur until the provider bulletin is published; AND
- prices proposed to the Department, counter offers from the Department, and final contracted prices shall not be **shared or announced** until the provider bulletin is published; AND
- Failure to comply with confidentiality requirements may result in a delay of the addition of products to the List, or cancellation of the contract.

Medical Supply/Enteral Formulas Review Criteria

The Department shall, when evaluating a decision to execute a contract, and when evaluating medical supplies/enteral formulas for retention on, addition to, or deletion from, the list of contract medical supplies/enteral formulas, use all of the following criteria:

(1) The safety of the medical supply/enteral formula.
(2) The effectiveness of the medical supply/enteral formula.
(3) The essential need for the medical supply/enteral formula.
(4) The potential for misuse of the medical supply/enteral formula.
(5) The cost of the medical supply/enteral formula.

The deficiency of a medical supply/enteral formula when measured by one of these criteria may

be sufficient to support a decision that the medical supply/enteral formula should not be added or retained, or should be deleted from the list. However, the superiority of a medical supply/enteral formula under one criterion may be sufficient to warrant the addition or retention of the medical supply/enteral formula, notwithstanding a deficiency in another criterion.

The Department's consideration of the five criteria follows:

(1) *Safety* means the relative freedom from side effects, and is determined by reviewing the contraindications, precautions, warnings, adverse effects, of the medical supply/enteral formula. Evaluation of safety may involve a single medical supply/enteral formula or comparisons between two or more medical supplies/enteral formulas, and may take into account such factors as safety of alternative methods of treatment, or the relationship of safety of a medical supply/enteral formula to the severity of prognosis of the medical conditions for which the medical supply/enteral formula is indicated.

(2) *Efficacy* means the speed, duration, and extent to which a medical supply/enteral formula will alleviate, control, or cure a medical condition. Evaluation of efficacy may involve a single medical supply/enteral formula or comparisons between two or more medical supplies/enteral formulas, and may take into account such factors as efficacy of alternative methods of treatment.

(3) *Essential Need* means that the availability of a medical supply/enteral formula through the List is necessary to protect life or prevent significant disability. Evaluation of essential need may involve a single medical supply/enteral formula or comparisons between two or more medical supplies/enteral formulas, and may take into account such factors as the availability of alternative methods of treatment, the incidence, severity and prognosis of the medical conditions for which a medical supply/enteral formula is indicated; whether a medical supply/enteral formula is a lifesaving agent or palliative in effect; or whether a medical supply/enteral formula may provide treatment for a medical condition not adequately treated by any other medical supply/enteral formula.

(4) *Misuse Potential* means the opportunity for unjustified, inappropriate, irresponsible, or improper use of a medical supply/enteral formula. Evaluation of unjustified, inappropriate, or irresponsible use may take into account such factors as: utilization of a medical supply/enteral formula where there is insufficient medical necessity for its use; continued use of a medical supply/enteral formula despite loss of effectiveness; and/or utilization of a medical supply/enteral formula where a less costly but equally safe and efficacious alternative may be used. Medical literature, staff, academic, and provider experience is utilized to confirm what uses are inappropriate.

(5) *Cost* means the cost of the product plus provider reimbursement, minus any rebate to the Department, if applicable.

Since other uses for medical supplies/enteral formulas are a reality in the marketplace, the Department takes such use into consideration when calculating costs and product usage.

As part of the cost evaluation, the Department considers data presented by the proposed contractor related to the comparison of two or more treatment alternatives having identical outcomes (Cost-Minimization Analysis), the comparison of treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis), or the comparison of total health care system cost of treatment alternatives having similar treatment outcomes (Cost-Effectiveness Analysis).

The guidelines for reviewing models/studies relative to evaluating the cost criterion are as follows:

1. Studies used to support claims must be of sufficient scientific rigor to assure confidence in the claimed effects. Study designs and measurements must reflect current scientific standards.

2. Baseline data should be reflective of the population covered by the Medi-Cal program.

3. Baseline data should be reflective of the Medi-Cal program.

4. Cost data should be reflective of the Medi-Cal program's reimbursement methods.

5. Realistic offsets for medical supply/enteral formula displacement should be included along with data quantifying product category growth.

Medical Supplies/Enteral Formulas Review Procedures

Individual medical supply/enteral formula may be reviewed and evaluated *either* as part of a Product Category Review (PCR), *or* an Individual Petition.

Product Category Review (PCR) Procedures

Product Category Reviews (PCRs) are self-initiated by the Department. It is the Department's intent to conclude a PCR within 180 days of the PCR Notification Letter. PCRs result in three year contracts between the Department and one or more contractors. A new PCR will be conducted approximately every three years. Products that do not meet contracting criteria (see page 2-3) or that are not proposed during a PCR may be proposed again in a subsequent PCR.

During the term of existing three year contracts, products that represent new technology and/or are assigned new Universal Product Numbers (UPN), Universal Product Codes (UPC), or National Drug Codes (NDC) will be considered for addition to the List via the Individual Petition Process (see page 6-8).

PCR Notification Letter

The PCR Notification Letter to the proposed contractors will include, at least, the following:

- Identification of the five criteria of: effectiveness, safety, essential need, misuse potential, and cost of the medical supply/enteral formula.
- Identification and phone number for the Department project manager assigned to coordinate the PCR.

PCR Analytical Process

The Department schedules and conducts a meeting with each proposed contractor. The Department's representatives at the meeting will generally include the Chief of Contract Unit A and the project manager assigned to coordinate the PCR. The purpose of this meeting is to discuss therapeutic considerations, studies, and the business proposal by the proposed contractor.

PCR Evaluation

The Department next conducts an internal meeting to review and evaluate the medical supply/enteral formula. Discussion of each medical supply/enteral formula is initiated by the project manager assigned to the PCR. A format is utilized for documenting consideration of each medical supply/enteral formula. This format includes the following information at a minimum:

- Proposed contractor of the medical supply/enteral formula.
- Brief documentation of each of the five criteria of safety, efficacy, essential need, misuse potential, and cost.
- Proposed contractor's input.
- Pertinent medical literature or other information.
- Department analysis.

PCR Negotiations

Following the Department's evaluation of the medical supply/enteral formula based on the five evaluation criteria, the Department may present a price counter offer to the proposed contractor. The proposed contractor may accept, reject, or present an alternative to the counter offer within the time frame requested by the Department.

PCR Decision

The project manager coordinates the Department's review of the medical supply/enteral formula. If during the internal review additional information is needed, the project manager will contact the proposed contractor. The Department then makes a decision about which products to add to or retain on the List.

PCR Decision Notification

The Department then sends a letter regarding the decision to the proposed contractor of the medical supply/enteral formula with identification and explanation of the five criteria upon which the decision was made.

When the decision is that a proposed contractor's medical supply/enteral formula will be added to, or retained on, the List, the Department will send a contract to the proposed contractor. Once the Department receives the contract signed by the proposed contractor's representative, the Department will instruct the Department's fiscal intermediary to inform providers of changes to the List and to take action for processing provider claims for these medical supplies/enteral formulas.

Proposed contractors may contact the project manager who coordinated the PCR to find out the proposed effective dates of the medical supply/enteral formula addition. The effective date to add a medical supply/enteral formula is not official until the Medi-Cal provider bulletin is published. Therefore, proposed contractors must not announce an effective date prior to Medi-Cal bulletin publication. The term of the resulting contract will be three years.

PCR Appeals

Contact your contract manager for information about appeals.

Individual Petition Review Procedures

To accommodate new medical supply/enteral formula technology or new UPN/UPC/NDCs an Individual Petition may be submitted for review and evaluation during the term of existing three year contracts. This process is reserved for these circumstances only.

Medical supply/enteral formula Individual Petition reviews occur as a result of proposed contractor requests, physician or pharmacist requests, or self-initiation by the Department. The Department will not begin a medical supply/enteral formula Individual Petition review unless the product has received appropriate marketing approval *and* the product is available on the market.

The Department logs in each Individual Petition received by proposed contractors and assigns a project manager to coordinate the review of a group of medical supplies/enteral formulas on a flow basis. Medical supply/enteral formula Individual Petitions may be deferred to a PCR if such a review is currently scheduled or planned.

Individual Petitions

To be considered complete, the Individual Petition must contain at least the following information regarding the medical supply/enteral formula:

- A letter specifically requesting addition to the List.

- Documentation of appropriate marketing approval.

The above minimum information is sufficient for the Department to initiate the review and evaluation of a single medical supply/enteral formula Individual Petition. However, the Department will require additional information during the review process. Proposed contractors are encouraged to provide the Department with detailed therapeutic (e.g., clinical studies) and cost information as early as possible in the review process to expedite the overall review. It is the Department's intent to conclude an Individual Petition review within 180 days of the Individual Petition Notification Letter.

Individual Petition Notification Letter

The Department will notify proposed contractors by mail that the review has been initiated. The Individual Petition Notification Letter includes at least the following:

- Identification of the five criteria (effectiveness, safety, essential need, misuse potential, and cost of the medical supply/enteral formula) used to evaluate the medical supply/enteral formula.
- Identification and phone number for the Department project manager assigned to coordinate the review.

Individual Petition Analytical Process

The Department schedules and conducts a meeting with the proposed contractor. The Department's representatives at the meeting will generally include the Chief of Contract Unit A and the project manager who has been assigned to coordinate the review. The purpose of this meeting is to discuss therapeutic considerations, studies, and the business proposal by the proposed contractor.

Individual Petition Evaluation

The Department's project manager next conducts an internal meeting to review and evaluate the medical supply/enteral formula. Discussion of each medical supply/enteral formula is initiated by the project manager assigned to the review. A format is utilized for documenting consideration of each medical supply/enteral formula. This format includes the following information at a minimum:

- Brief documentation of each of the five criteria of safety, efficacy, essential need, misuse potential, and cost.
- Proposed contractor's input.
- Pertinent medical literature or other information.
- Department analysis.

Individual Petition Negotiations

Following the Department's evaluation of the medical supply/enteral formula based on the five evaluation criteria, a price counter offer may be presented to the proposed contractor. The proposed contractor may accept, reject, or present an alternative to the price counter offer within the time frame requested by the Department.

Individual Petition Decision

The project manager assigned to coordinate the review initiates final discussions on the medical supply/enteral formula if any additional information and business proposals have been offered by the proposed contractor. Upon completion of these discussions, a decision is made whether or not to add the Petitioned product to the List.

Individual Petition Decision Notification

The Department then sends a letter regarding the decision to the proposed contractor of the medical supply/enteral formula with identification and explanation of the five criteria upon which the decision was made.

When the decision is that a proposed contractor's medical supply/enteral formula will be added to the List, the Department will send a contract to the proposed contractor. Once the Department receives the contract signed by the proposed contractor's representative, the Department will instruct the Department's fiscal intermediary to inform providers of changes to the List and to take necessary action for processing provider claims for these medical supplies/enteral formulas.

Proposed contractors may contact the project manager who coordinated the review to find out the proposed effective date of the medical supply/enteral formula addition. The effective date to add a medical supply/enteral formula <u>is not</u> official until the Medi-Cal provider bulletin is published. Therefore, proposed contractors <u>must not</u> announce an effective date prior to Medi-Cal bulletin publication.

Individual Petition Appeals

Contact your contract manager for information about appeals.